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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,119	12/30/2003	Richard L. Boyd	286336.152US1/NOR-013CP2	3286

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WILMER CUTLER PICKERING HALE AND DORR LLP  
60 STATE STREET  
BOSTON, MA 02109

EXAMINER
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LI, QIAN JANICE

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	03/01/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 03/01/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

teresa.carvalho@wilmerhale.com  
tina.dougal@wilmerhale.com  
michael.mathewson@wilmerhale.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/749,119	<b>Applicant(s)</b> BOYD, RICHARD L.	
	<b>Examiner</b> Q. Janice Li, M.D.	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-26, 28-40, 42-44, 46-49 and 53-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 19-26, 28-40, 42-44, 46-49 and 53-75 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 19-26, 28-40, 42-44, 46-49, 53-75 are pending and subject to the following restriction requirement.

#### ***Claim Objections***

Claims 38, 68 are objected to because they depend from themselves. For the sake of a compact prosecution, applicant is responsible to correct the deficiency and indicate which of the following groups claims 38, 68 belong to.

#### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 19-26, 28-37, 39, 40, 42-44, 46-49, 53, 55-66, 71, 72, 74, 75 are drawn to a method of inducing graft tolerance in a patient, wherein the method comprising depleting T cells of the patient. Classified in class 424, subclass 93.1.
- II. Claims 54 are drawn to a method for increasing virus-specific peripheral T cell responsiveness of a patient. Classified in class 424, subclass 93.1.
- III. Claims 67, 73 are drawn to a method of inducing graft tolerance in a patient, wherein the method does not comprise depleting T cells of the patient. Classified in class 424, subclass 93.1.

- IV. Claims 69, 70 are drawn to a method of inducing graft tolerance in a patient, wherein the method comprising providing the patient with an immunosuppressive therapy. Classified in class 424, subclass 93.1.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-IV and I are directed to related inventions. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions have materially different design and mode of operation, and mutually exclusive. For example, invention group I contains the step of T cell depletion, which are not required or even forbidden in groups II-IV. Invention group II has different goal compared to any of the invention groups III, IV, and I.

The differences of the Inventions I-IV are further underscored by their divergent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, a serious burden is imposed on the Office to perform a complete search of the defined areas in both the patent and non-patent literature if all the groups are examined together. Therefore, the restriction set forth is

proper and not to restrict would impose a serious burden in the examination of this application.

3. This application contains claims directed to patentably distinct species of the claimed invention. Upon election of an invention for examination in this application, further election of a species is necessary, wherein the species is defined by a **combination** of the following factors:
  - A. a specific means and timing of T cell depletion (such as radiation or a drug, before or after thymus reactivation (applicable to group I); or a specific means of immunosuppression (applicable to group IV).
  - B. a specific cause of thymus atrophy (e.g. post-puberty, a specific disease).
  - C. a specific means of thymus reactivation, such as disruption of sex steroid mediated signaling by administering one of the drugs recited in claim 36; if the reactivation requires administering a growth factor, indicate a specific growth factor or a specific combination of growth factors, such as one of those recited in claim 40.
  - D. A specific cell type administered, such as one selected from the group consisting of hematopoietic cells, dendritic cells, epithelial stem cells, embryonic stem cells, and myeloid progenitor cells; in the case that the cells are genetically modified, indicate a specific genetic modification.
  - E. A specific cell/organ graft and target organ, where the tolerance is desirable, such as hematopoietic stem cell graft to thymus organ.
  - F. The donor relative to recipient: allogeneic or xenogenic.

Each of the listed species encompasses structurally and functionally distinct subject matter, using divergent starting material, and not overlap in structure search. Thus, a search and examination of anything more than one of such together for patentability would be unduly burdensome to the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of A through F, even though this requirement is traversed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 19, 20, 42, 53, 54, 66, 67, 69, 73 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

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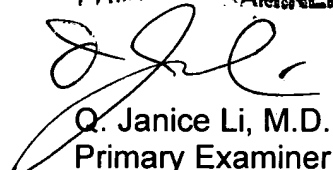
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on 571-272-0739. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

**Q. JANICE LI, M.D.**  
**PRIMARY EXAMINER**



Q. Janice Li, M.D.  
Primary Examiner  
Art Unit 1632

QJL  
February 20, 2007